

IN THE ABSTRACT: Kindly replace the Abstract with the Substitute Abstract Sheet provided herewith.

REMARKS

The applicants acknowledge the Examiner's comprehensive Office Action with appreciation. Claims 19-24 remain under consideration. The Office raises rejections under 35 USC § 112, first paragraph. The Office also raises objections as to form.

The Office states that, according to 37 CFR § 1.78(a)(2) and (a)(5), an application in which the benefits of an earlier application are desired must contain a specific reference to the prior application in the first sentence of the specification *or* in an Application Data Sheet and that the specific reference must include the relationship between the applications. The Applicants respectfully submit that the required reference to US Serial No. 10/400,358, of which the instant application is a division, was included in the Application Data Sheet filed with the instant application.

The Office objects to the Abstract based on the term "Medicaments" which appears by itself at the end of the Abstract. With the instant Response, the Applicants have submitted a Substitute Abstract Sheet in which the term "medicaments" has been incorporated into the final clause of the Abstract for the sake of clarity.

Claims 19-24 are rejected for lack of written description under 35 USC § 112, first paragraph. It is the position of the Office that conditions claimed to be treatable with the instant compounds, i.e., "cognitive disorders, impulsive disorders, disorders of the libido and sexual dysfunctions, sleep disorders, and appetite disorders" include as yet unidentified "cognitive disorders, impulsive disorders, disorders of the libido and sexual dysfunctions, sleep disorders, and appetite disorders" which are not described in the instant specification.

Claims 19-24 are also rejected for lack of enablement under 35 USC § 112, first paragraph. It is the position of the Office that the specification, while being enabling

for treating depression, bulimia and anorexia, and for inhibiting penile erection, does not reasonably provide enablement for treatment of all the conditions claimed. It is the position of the Office that the cited references (Winjingaarden, et al. and Barnes, et al.) demonstrate that correlation between treatment of all the claimed conditions and antagonism at the 5-HT_{2C} receptor site has not been established.

The Office acknowledges that the instant Specification demonstrates that representative compounds of the instant invention exhibit activity as 5-HT_{2C} receptor antagonists. With this Response and Amendment, the Applicants provide a Declaration by Dr. Mark MILLAN, a scientist skilled in this particular art, which speaks to the 35 USC § 112, first paragraph rejections. The Declaration addresses the correlation between receptor binding affinity at the 5-HT_{2C} receptor sites and the treatment of specific disease states. Specifically, the Declarant provides a review of published literature demonstrating that those skilled in the art understand that compounds which possess potent binding affinity at the 5-HT_{2C} receptors have a definite and positive utility in the treatment of anxiety, depression, sexual dysfunction, schizophrenia, sleep disorders, drug abuse, impulsive disorders, libido disorders, cognitive disorders, and Parkinson's disease.

Moreover, the Applicants submit an additional reference (SM-3163, *Pharmaproject*, 2005) which describes the 5-HT₂ antagonist, SM-3163, as a "cognition enhancer" which may be used to improve learning and memory. Therefore, the Applicants submit that one skilled in the art would recognize what is meant by the term "cognitive disorders."

The Applicants have provided written description commensurate with the skill in the art. That those skilled in the art utilize these terms in their communication demonstrates that these terms have discrete meaning. The purpose of the patent disclosure is to demonstrate that the Applicant has possession of the invention claimed, not that the Applicant has the ability to search for every possible variation on discrete conditions. Those skilled in the art comprehend the terms which the Office enumerates as including as yet undefined conditions. The standard for such evaluation is whether those terms are sufficiently defined so as not to require further

experimentation to elucidate the nature of the disclosure. It is submitted that the instant Declaration demonstrates that such conditions are well defined according to the standards of the art. The compounds of the instant invention are claimed to treat the disorders enumerated regardless of whether such disorders will be identified under a different name at some time in the future.

The Applicants submit that they have complied with the written description requirement and that the instant invention is enabled with respect to the treatment of the specific conditions claimed. Reconsideration and withdrawal of the rejections under 35 USC § 112, first paragraph, is respectfully requested.

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Accordingly, entry of the MILLAN Declaration and the present amendment, reconsideration of all grounds of objection and rejection, withdrawal thereof, and passage of this application to issue are all hereby respectfully solicited.

It should be apparent that the undersigned attorney has made an earnest effort to place this application into condition for immediate allowance. If he can be of assistance to the Examiner in the elimination of any possibly-outstanding insignificant impediment to an immediate allowance, the Examiner is respectfully invited to call him at his below-listed number for such purpose.

Allowance is solicited.

Respectfully submitted,

THE FIRM OF HUESCHEN AND SAGE

By: 

G. PATRICK SAGE

Dated: March 14, 2005
Customer No.: 25,666
500 Columbia Plaza
350 East Michigan Ave.
Kalamazoo, MI 49007-3856
(269) 382-0030

Enclosure: PTO-Form 1449 and Accompanying References (references 8, 21, and 22 to follow under separate cover); MILLAN Declaration; Substitute Abstract Sheet; Fee for Two (2) Month Extension; and Postal Card Receipt

THE COMMISSIONER IS HEREBY AUTHORIZED TO CHARGE ANY FURTHER OR ADDITIONAL FEES WHICH MAY BE REQUIRED (DUE TO OMISSION, DEFICIENCY, OR OTHERWISE), OR TO CREDIT ANY OVERPAYMENT, TO DEPOSIT ACCOUNT NO. 08,3220.